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PUBLIC HEALTH SERVICE

PHS INTERINSTITUTIONAL AGREEMENT

INSTITUTION-LEAD

This **Agreement** is entered into between the National Institutes of Health ("**NIH**") or the Food and Drug Administration ("**FDA**"), hereinafter singly or collectively referred to as "**PHS**", agencies of the United States Public Health Service within the Department of Health and Human Services ("**HHS**") through the Office of Technology Transfer, **NIH**, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, U.S.A and _____, hereinafter referred to as the "**Institution"**, having an address at _____.

1. BACKGROUND

1.1 In the course of fundamental research programs at the **PHS** and by the **Institution**, under a **HHS** funding agreement (Grant/Contract No. _____), _____ (**Inventor(s)**) made or reduced to practice certain inventions which are included within the **Patent Rights**, as defined in Paragraph 2.1.

1.2 It is the mutual desire of the **Institution** and the **PHS** that their respective undivided interests in the **Patent Rights** be administered in a manner to ensure the rapid commercialization of the **Patent Rights** and to make their benefits widely available to the public. Therefore, in accordance with 35 U.S.C. §202(e) and 37 CFR §401.10, **PHS** is granting an exclusive license to **PHS'** rights in the **Patent Rights** to the **Institution** under the conditions set forth herein.

2. DEFINITIONS

2.1 "**Patent Rights**" means:

(a) Patent applications (including provisional patent applications and PCT patent applications) or patents as follows: U.S. Patent Application Serial No./U.S. Provisional Patent Application Serial No. ____/_____,_____, filed _____, entitled _____, and any patent application(s) claiming the benefit of priority thereof including all divisions and continuations of these applications, all patents issuing from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all these patents to the extent that at least one **Inventor** from the **Institution** is an **Inventor** thereon;

(b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.1(a) and to the extent that at least one **Inventor** from the **Institution** is an **Inventor**:

(i) continuations-in-part of 2.1(a);

(ii) all divisions and continuations of these continuations-in-part;

(iii) all patents issuing from these continuations-in-part, divisions, and continuations;

(iv) priority patent application(s) of 2.1(a); and

(v) any reissues, reexaminations, and extensions of all these patents; and

(c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.1(a) and to the extent that at least one **Inventor** from the **Institution** is an **Inventor**: all counterpart foreign and U.S. patent applications and patents to 2.1(a) and 2.1(b); and

(d) **Patent Rights** shall *not* include 2.1(b) or 2.1(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.1(a).

2.2 "**Net Revenues**" means all consideration received by the **Institution** from the licensing of the **Patent Rights** pursuant to this **Agreement**, less (a) **Expenses** and then (b) _____ percent (X%) of the remaining consideration for administrative overhead wherein said administrative overhead is not to exceed _____ dollars ($X).

2.3 "**Expenses**" means all reasonable and actual out-of-pocket costs, excluding those reimbursed by a third party, incurred by the **Institution** for the preparation, filing, prosecution, and licensing of United States and foreign patent applications, extraordinary expenses as provided in Paragraph 4.6, and the maintenance of the resulting patents or patent applications, exclusive of any salaries, administrative, or other indirect costs.

2.4 "**Research License**" means a nontransferable, nonexclusive license to make and to use any tangible embodiment of the **Patent Rights** and to practice any process(es) included within the **Patent Rights** for purposes of internal research and not for purposes of commercial manufacture or distribution or in lieu of purchase.

2.5 "**Practical Application**" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or by regulations of the Government of the United States of America (hereinafter referred to as "**Government**"), available to the public on reasonable terms.

3. GRANT AND RESERVATION OF RIGHTS

3.1 **PHS** hereby grants and the **Institution** accepts, subject to the terms and conditions of this **Agreement**, an exclusive license, including the right to sublicense, under the **Patent Rights** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any tangible embodiment of the **Patent Rights** and to practice and have practiced any process included within the **Patent Rights**.

3.2 The **Government** shall have the irrevocable, royalty-free, paid-up right to practice and have practiced the **Patent Rights** throughout the world by or on behalf of the **Government** and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement to which the **Government** is a signatory. Any license granted by the **Institution** under the terms of this **Agreement** shall be subject to this right of the **Government**.

3.3 **PHS** reserves the right to require the **Institution**, or its licensees, to grant sublicenses to responsible applicants, on terms that are reasonable under the circumstances when necessary to fulfill health or safety needs or when necessary to meet requirements for public use specified by Federal regulations.

3.4 In addition to the reserved right of Paragraph 3.3, **PHS** reserves the right to require **Institution** to grant **Research Licenses** on reasonable terms and conditions. The purpose of these **Research Licenses** is to encourage basic research, whether conducted at an academic or corporate facility.

4. PATENT PROSECUTION AND PROTECTION

4.1 The **Institution** shall file, prosecute, and maintain patent application(s) relating to the **Patent Rights** and shall promptly provide to **PHS** all serial numbers and filing dates, together with copies of all these applications, including copies of all Patent Office actions, responses, and all other Patent Office communications. In addition, the **Institution**, shall file with Patent Offices, a Power of Attorney, that names both the **Institution** and **PHS**. This Power of Attorney shall be filed with every Patent Office involved in prosecuting all patent applications pertaining to **Patent Rights**. The **Institution** shall consult with **PHS**, when so requested, prior to communicating with any Patent Office with respect to the **Patent Rights**.

4.2 The **Institution** shall make an election with respect to foreign filing, upon consultation with **PHS**, including which countries foreign filing shall be done prior to the election, within eight (8) months of any United States filing. If any foreign patent applications are filed, the **Institution** shall promptly provide to **PHS** all serial numbers and filing dates. The **Institution** also shall provide **PHS** copies of foreign patent applications and Patent Office actions. The **Institution** shall consult with **PHS**, when so requested, prior to communication with any Patent Office with respect to the **Patent Rights**.

4.3 The **Institution** shall promptly record Assignments of domestic **Patent Rights** in the United States Patent and Trademark Office and shall promptly provide **PHS** with the original of each recorded Assignment with respect to **PHS**.

4.4 Notwithstanding any other provision of this **Agreement**, the **Institution** shall not abandon the prosecution of any patent application, including provisional patent applications (except for purposes of filing continuation application(s)) or the maintenance of any patent contemplated by this **Agreement**, without prior written notice to **PHS**. Upon receiving the written notice, **PHS** may, at its sole option, take over the prosecution of any patent application, or the maintenance of any patent.

4.5 The **Institution** shall promptly provide **PHS** with copies of all issued patents under this **Agreement**.

4.6 In the event that the **Institution** anticipates the possibility of any extraordinary expenditures arising from the preparation, filing, prosecution, licensing, or defense of any patent application or patent contemplated by this **Agreement**, including, without limitation, interferences, reexaminations, reissues and oppositions, the **Institution** shall provide **PHS** with all relevant information, and these extraordinary expenditures shall be included as **Expenses** only upon written agreement of **PHS**. The **Institution** and **PHS** shall agree on a mutually acceptable course of action prior to incurring these expenditures.

5. LICENSING

5.1 The **Institution** shall diligently seek licensees for the commercial development of the **Patent Rights** and shall administer the **Patent Rights** for the mutual benefit of the parties and in the public interest. The **Institution** shall ensure that any license granted for the **Patent Rights** is subject to the provisions of 37 C.F.R. Part 401 and the rights retained by the **Government** under this **Agreement**, including the requirement for substantial manufacture in the United States as stated in Paragraph 11.1.

5.2 The **Institution** shall not issue any royalty-free or paid-up licenses or assign **Patent Rights** to any third party, notwithstanding any other provision of this **Agreement**, without the prior written consent of **PHS**.

5.3 The **Institution** shall consult with **PHS** in the negotiation of any exclusive or partially-exclusive licenses, not withstanding any other provision of this **Agreement**, and shall not grant these licenses without the prior review, opportunity for comment, and written approval of **PHS**.

5.4 Before licensing of the **Patent Rights** or any part thereof by the **Institution**, the **Institution** shall first notify and confer with **PHS** regarding any research funding related to the **Patent Rights** so as to determine **PHS'** interest in participating in any funded collaborative research project.

5.5 The **Institution** shall promptly provide **PHS** with complete copies of all licenses and sublicenses granted for the **Patent Rights**.

5.6 **Institution** agrees that its licensees shall supply, to the Mailing Address for **Agreement** notices indicated on the Signature Page, the Office of Technology Transfer, **NIH** with inert samples of the licensed products or licensed processes, as covered by the **Patent Rights**, or their packaging for educational and display purposes only.

6. ROYALTIES AND EXPENSES

6.1 The **Institution** shall distribute **Net Revenues** to **PHS** concurrently with distributions it makes under the **Institution's** patent policy, but in any case not later than April 1 for the preceding calendar year, on the following basis: (a) _____ percent (X%) of the **Net Revenues** as a royalty to the **Institution** and (b) _____ percent (X%) of the **Net Revenues** as a royalty to **PHS**.

6.2 All payments to **PHS**, required under this **Agreement**, shall be in U.S. dollars and payment options are listed in Appendix A.

(a) Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by **Institution**; and

(b) Additional royalties may be assessed by **PHS** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by **PHS** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.

6.3 **Institution** shall submit to **PHS** annual statements of itemized **Expenses** and shall deduct the **Expenses** as defined in Paragraph 2.3, except where **PHS** has identified discrepancies in billing by **Institution**, in which case, deduction of the contested item(s) from **Net Revenues** shall be delayed pending resolution thereof.

6.4 Each party shall be solely responsible for calculating and distributing to its respective **Inventor(s)** of the **Patent Rights** any share of **Net Revenues** in accordance with its respective patent policy, royalty policy, or Federal law during the term of this **Agreement**.

7. RECORDS AND REPORTS

7.1 The **Institution** shall keep complete, true, and accurate accounts of all **Expenses** and of all **Net Revenues** received by it from each licensee of the **Patent Rights** and shall permit **PHS** or **PHS'** designated agent to examine its books and records in order to verify the payments due or owed under this **Agreement**.

7.2 Upon request by **PHS**, the **Institution** shall submit to **PHS** an annual report, not later than April 1 of each year, setting forth the status of all patent prosecution, commercial development, and licensing activity relating to the **Patent Rights** for the preceding calendar year.

8. PATENT INFRINGEMENT

8.1 In the event **PHS** or the **Institution**, including its licensees, shall learn of the substantial infringement of any patent subject to this **Agreement**, the party who learns of the infringement shall promptly notify the other party in writing and shall provide the other party with all available evidence of the infringement. The **Institution** and its licensees, in cooperation with **PHS**, shall use their best efforts to eliminate the infringement without litigation. If the efforts of the parties are not successful in eliminating the infringement within ninety (90) days after the infringer has been formally notified of the infringement by the **Institution**, the **Institution** shall have the right, after consulting with **PHS**, to commence suit on its own account. **PHS** may join the **Institution's** suit or commence its own suit.

8.2 The **Institution** may permit its licensees to bring suit on their own account, but only if **PHS** and the **Institution** elect not to commence separately or join each other in any suit, other than as nominal party plaintiff, either by formal notice or by failure to act within the ninety (90) day period set forth in Paragraph 8.1. **PHS** shall retain the right to join any licensee's suit.

8.3 Neither a licensee nor the **Institution** shall take action to compel **PHS** either to initiate or to join in any suit for patent infringement. Should the **Government** be made a party to any suit by motion or any other action of a licensee or the **Institution**, the licensee or the **Institution** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of the motion or other action, including any and all costs incurred by **PHS** in opposing any joinder action.

8.4 Legal action or suits to eliminate infringement or recover damages pursuant to Paragraph 8.1 shall be at the full expense of the party by whom suit is brought. All damages recovered thereby shall first be used to reimburse each party for its expenses relating to the legal action, and the remainder of the damages shall be considered **Net Revenues**.

8.5 Each party agrees to cooperate with the other in litigation proceedings. **PHS** may be represented, at its expense, by counsel of its choice in any suit.

9. GOVERNING LAWS, SETTLING DISPUTES

9.1 This **Agreement** shall be construed in accordance with U.S. Federal law, as interpreted and applied by the U.S. Federal courts in the District of Columbia. Federal law and regulations shall preempt any conflicting or inconsistent provisions in this **Agreement**. The **Institution** agrees to be subject to the jurisdiction of U.S. courts.

9.2 Any controversy or any disputed claim by either party against the other arising under or related to this **Agreement** shall be submitted jointly to the **Institution's** President or designee and to the Director of the **NIH** or designee for resolution. The **Institution** and **PHS** shall be free after written decisions are issued by those officials to pursue all administrative or judicial remedies which may be available.

10. TERM AND TERMINATION

10.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 11.9 are not fulfilled, and shall extend to the expiration of the last to expire of the patents included within the **Patent Rights** unless otherwise terminated by operation of law or by acts of the parties in accordance with the terms of this **Agreement**.

10.2 The **Institution** may terminate this **Agreement** upon at least sixty (60) days written notice to **PHS**, but in any event not less than sixty (60) days prior to the date on which any pending Patent Office actions need be taken to preserve patent rights for the benefit of the parties hereto.

10.3 In the event the **Institution** has made no commitments to any third party for exclusive license rights relating to the **Patent Rights**, **PHS** may terminate this **Agreement** for any reason upon thirty (30) days written notice to the **Institution**. During the term of any option agreement or license agreement to any third party for exclusive license rights relating to the **Patent Rights** between the **Institution** and an optionee or licensee, **PHS** may terminate this **Agreement** when:

(a) it is determined by **PHS'** Office of Technology Transfer that:

(i) The **Institution** or its licensee has not taken and is not expected to take effective steps to achieve **Practical Application** of the **Patent Rights**;

(ii) Termination is necessary to alleviate health or safety needs which are not reasonably satisfied by the **Institution** or its licensee;

(iii) Termination is necessary to meet requirements for public use specified by Federal law or regulations and these requirements are not reasonably satisfied by the **Institution** or its licensees; or

(iv) Termination is necessary because the requirements of 35 U.S.C. §204 have not been satisfied or waived or because a licensee of the exclusive right to use or sell the **Patent Rights** in the United States is in breach of its agreement obtained pursuant to Section 204;

(b) the **Institution** or affected third party has been notified of this determination and has been given at least thirty (30) days to provide a response to this determination, and

(c) the **Institution's** or affected third party's response to the determination of 10.3(a)(i)-(iv) is determined to be unsatisfactory by the Office of Technology Transfer.

10.4 **PHS** may terminate this **Agreement** in whole or in part if:

(a) the **Institution** fails to make any payment or periodic reports required by this **Agreement**;

(b) the **Institution** has willfully made a false statement of, or willfully omitted, a material fact in the negotiation of the **Agreement** or in any report required by the **Agreement**;

(c) the **Institution** has committed a substantial breach of a covenant or duty contained in this **Agreement**; or

(d) **PHS** and the **Institution** are involved in a dispute under this **Agreement** which cannot be resolved under the procedures specified in Paragraph 9.2. If the **Agreement** is terminated under this Paragraph 10.4, **PHS** agrees to provide affected licensees an opportunity to license the **Patent Rights** subject to the restrictions of 37 CFR Part 404, under terms as may have been agreed to by the **Institution**.

10.5 Following termination by **PHS**, **PHS** shall have no further rights or obligations under this **Agreement**, except that the **Institution** shall be obligated to administer subsequent gross proceeds from licensing the **Patent Rights** according to the **Institution** policy, and to distribute royalties to **PHS** for **PHS Inventor(s)** as though they were **Inventor(s)** of the **Institution** under that policy with respect to royalties and payment schedules.

11. GENERAL

11.1 The **Institution** agrees that, for use and sale of the **Patent Rights** in the United States, any products embodying the **Patent Rights**, or produced through use of the **Patent Rights**, shall be manufactured substantially in the United States unless a waiver is granted by **PHS**.

11.2 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to the other address as may be designated in writing by such other party. **Agreement** notices shall be considered timely if the notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

11.3 This **Agreement** shall not be construed to confer on any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to this **Agreement** shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

11.4 It is agreed that no waiver by either party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent or similar breach or default.

11.5 This **Agreement** is binding upon and shall inure to the benefit of the parties hereto and their successors or assigns, but this **Agreement** may not be assigned by either party without the prior written consent of the other party.

11.6 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the **PHS** other than the **Patent Rights** regardless of whether such patents are dominant or subordinate to the **Patent Rights**.

11.7 Any modification to this **Agreement** must be in writing and agreed to by both parties.

11.8 It is understood and agreed by the **Institution** and **PHS** that this **Agreement** constitutes the entire agreement between the parties, and that all prior agreements respecting the subject matter hereof, either written or oral, expressed or implied, shall be abrogated, canceled, and are null and void and of no effect.

11.9 The terms and conditions of this **Agreement** shall, at **PHS**' sole option, be considered by **PHS** to be withdrawn from **Institution's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Institution** and a fully executed original is received by **PHS** within sixty (60) days from the date of **PHS** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

PHS INTERINSTITUTIONAL AGREEMENT – INSTITUTION

SIGNATURE PAGE

IN WITNESS WHEREOF, the parties hereto have executed this **Agreement** in duplicate originals by their respective duly authorized officers, who have affixed their signatures hereunto, on the day and year hereinafter written. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For **PHS**:

_____ _____

Steven M. Ferguson — Date
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Mailing Address for **Agreement** notices:

Chief, Monitoring & Enforcement Branch, DTDT
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

For the **Institution**:

Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the **Institution** made or referred to in this **Agreement** are truthful and accurate.

_____ _____

Signature of Authorized Official — Date

_____

Printed Name

_____

Title

Official and Mailing Address for **Agreement** notices:

_____

_____

_____

Official and Mailing Address for Financial notices (**Licensee's** contact person for royalty payments)

_____

Name

_____

Title

Mailing Address:

_____

_____

_____

_____

Email Address: _____

Phone: _____

Fax: _____

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

APPENDIX A – ROYALTY PAYMENT OPTIONS

NIH/PHS License Agreements

****In order to process payment via Electronic Funds Transfer sender MUST supply the following information:***

Procedure for Transfer of Electronic Funds to NIH for Royalty Payments

Bank Name: Federal Reserve Bank

ABA# 021030004
TREAS NYC
BNF=/AC-75080031
OBI=Licensee Name and OTT Reference Number
Dollar Amount Wired=$$

NOTE: Only U.S. banks can wire directly to the Federal Reserve Bank. Foreign banks cannot wire directly to the Federal Reserve Bank, but must go through an intermediary U.S. bank. Foreign banks may send the wire transfer to the U.S. bank of their choice, who, in turn forwards the wire transfer to the Federal Reserve Bank.

Mailing Address for Royalty Payments:

National Institutes of Health
P.O. Box 360120
Pittsburgh, PA 15251-6120 USA

Overnight Mail for Royalty Payments only

National Institutes of Health
360120
Mellon Client Service Center
Room 670
500 Ross Street
Pittsburgh, PA 15262-0001

(412)234-4381 (Customer Service)

Please make checks payable to: *NIH/Patent Licensing*

*The OTT Reference Number **MUST** appear on checks, reports and correspondence*